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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,290	11/28/2001	Thomas Terwee	10806-154	4031
24256	7590	08/11/2004	EXAMINER	
DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			LANDREM, KAMRIN R	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/996,290

Applicant(s)

TERWEE ET AL.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) 40,51-54,58,59 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-39,41-50, 55-57, 60-71, 73-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33, 44-50, 55-57, 60-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Tahi et al (USPN6,358,279 B1).

With reference to Figures 2 and 3, Tahi discloses a sealing device 100 adapted to compensate for aberration comprising a transparent disc-shaped flexible plug 110 made of a deformable silicon polymer (5: 30-51) having a slightly larger area than the incision adapted to seal a capsulorhexis of a capsular bag. The sealing device further comprises an anteriorly protruding adjusting means 112 that is removable at fastening point 140 (Figure 1b) and admits an injection device 118 for injecting a liquid material (7:46) capable of preventing epithelial cell growth (7:34-36). The plug 110 and the adjusting means 112 in combination comprise the sealing device. No other means besides the sealing device are used to seal the excised areas. Upon removal of the delivery means 118 the plug 110 retains a sealed position thereby preventing the displacement of lens forming liquid from the capsular bag. (6:1-14). The flexible anteriorly protruding (8:37-38) adjusting means 112 is removed after injection of lens forming material (9:4-9). The plug member can be positioned in a rhexis of more than 1mm in diameter

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(8:4-6) and can remain in the capsular bag after lens formation (5:53-55) or can likewise be removed after lens formation (7:54-55).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-39 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tahi et al.

Tahi, as discussed supra, discloses the method of positioning a sealing device 100 comprising a flexible plug 110 and removable adjusting means 112 wherein the adjusting means is located so that the peripheral anterior surface of plug 110 contacts the inner posterior wall (7:4-7) to seal a capsulorhexis opening creating during ocular surgery. The adjusting means 112 is removed after implantation (9:4-9). Tahi does not specifically recite that the injection of the lens forming material exerts sufficient pressure on posterior side of plug to seal the excised area. It is inherent that the filling of the capsular bag would increase the volume of the capsular bag and thereby creates a pressure that would exert force against the wall of the capsular bag. This pressure would thereby result in the sealing device being compressed against the interior wall of the capsular bag and thereby strengthen the seal to prevent leakage of the lens material. If not inherent, it therefore would have been obvious to one of ordinary skill in the art at the time the invention was made to inject an amount of lens forming material that would result in increased

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pressure and create an enhanced sealing between the plug and the inner posterior wall of the capsular bag.

Claims 41-43 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tahi as applied to claims 34,44, and 68 and above, and further in view of Werblin (USPN 6,413,276).

Tahi, as discussed supra, discloses the method and sealing device as claimed. Tahi does not disclose the method of measuring the cornea and the amount of aberrations to select a sealing device to compensate for these aberrations. Werblin teaches the method of measuring the aberrations of the eye and using this data to create a surface to correct for the aberrations/abnormalities on the eye or a customized optical element, such as an intraocular lens (7:1-10). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of measuring the amount of the aberrations of the eye as taught by Werblin to before inserting a sealing device 100 as disclosed by Tahi to insure that the device comprises a surface that is capable of compensating and correcting aberrations and abnormalities.

### ***Response to Arguments***

Applicant's arguments filed 5/13/04 have been fully considered but they are not persuasive. The applicant's arguments that member 112 is an additional sealing means is unpersuasive. The Examiner contends that the plug 110 and member 112 together form the "sealing device". No other means are used to seal the plug. Tahi does disclose a sealing device (plug 110 and member 112) for a capsulorhexis that leaves no permanent parts outside after the lens implantation process is finalized because member 112 is removed from the plug 110. Tahi

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does in fact disclose filling the capsular bag with lens forming material. One would realize that such filling of the capsular bag would generate fluid pressure. Upon injection of capsular filling material the plug would be pushed or held in position by the pressure generated from filling the capsular bag with fluid. Applicant's arguments are unpersuasive and amendments fail to distinguish the structure claimed by Applicant over that of Tahi.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem  
Examiner  
AU 3738

krl

  
**CORRINE McDERMOTT**  
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